

Exhibit 4



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"I will stand for my client's rights.
I am a trial lawyer."
-Ron Motley (1944-2013)

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January 8, 2019

VIA EMAIL

Special Master David R. Cohen
Carl B. Stokes U.S. Courthouse
801 West Superior Avenue
Cleveland, OH 44113-1837
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RE: In Re National Prescription Opioid Litigation, Case No. 17-md-2804; Plaintiffs' Response to Manufacturer Defendants' Renewed Motion to Compel Immediate and Full Compliance with Discovery Ruling Nos. 5 and 13

Dear Special Master Cohen:

This letter shall serve as Plaintiffs' Response in Opposition to Manufacturer Defendants' January 4, 2018 Renewed Motion to Compel Immediate and Full Compliance with Discovery Ruling Nos. 5 and 13. Plaintiffs in the three Track One bellwether cases ("Plaintiffs") have fully complied with both Discovery Ruling 5 and 13, and have fully responded to Manufacturer Interrogatory Nos. 6, 7, and 10.

Plaintiffs complied with Discovery Ruling 13 by responding to Manufacturer Interrogatory No. 6. In their answer, Plaintiffs identified the requisite specific 500 prescriptions required by Discovery Ruling 5 and have sufficiently identified the connections between the prescriptions and the misstatements at issue. Nonetheless, in an effort to compromise, Plaintiffs will agree to identify additional prescriptions using a lesser threshold (120 MME/day).

With respect to medical claims information concerning those prescriptions, Plaintiffs have never been in possession of the claims data Defendants are requesting. Regardless, Plaintiffs remain unable to provide any such data due to the restrictions set forth in Title 42, Part 2 of the Code of Federal Regulations ("Part 2"). As has been previously briefed, Part 2 is a broad provision that precludes disclosure of information that constitutes a diagnosis from a "Part 2 Provider" and "[w]ould identify a patient as having or having had a substance use disorder." 42 C.F.R. § 2.12(a). Due to the criteria used to identify these prescriptions, a significant number of the medical claims would fall within Part 2's restrictions. Unless Defendants are willing to destroy all copies of previously provided information and accept a fully de-identified list, federal law precludes Plaintiffs from providing medical claims information to accompany the pharmacy claims that have been or will be disclosed.

Special Master Cohen

January 8, 2019

Re: Response to Manufacturer Defendants' Renewed Motion to Compel

Page 2

Moreover, the information provided by Plaintiffs in responding to Interrogatory Nos. 6, 7 and 10 is fully sufficient to give Defendants the information they need to defend themselves. The spreadsheet produced to Defendants includes:

the manufacturer name

the provider name

the record and patient key numbers

patient full name

patients' date of birth

patient's gender

patient's full address

the Prescriber's DEA number

the prescriber's full address

the pharmacy name

the pharmacy address

the date the prescription was filled

the National Drug Code for the drug prescribed the drug name

the drug strength

the quantity

the days supplied

the amounts paid by the patient

the amounts paid by insurance

Indeed, Defendants' Motion to Compel does not claim they cannot defend themselves or prepare their case using the information provided by Plaintiffs; instead, they are complaining that Plaintiffs have not provided *enough* examples. In addition, this Motion to Compel comes despite Plaintiffs' repeated assurances that they plan to prove their case with aggregate, and not individualized proof. Plaintiffs chose to respond to Interrogatory Nos. 6, 7 and 10 so as not to be limited by the Court's ruling in Discovery Ruling 5 in ways that cannot be anticipated at this stage of the case and to

Special Master Cohen

January 8, 2019

Re: Response to Manufacturer Defendants' Renewed Motion to Compel

Page 3

preserve their right to present additional evidence as needed based on Defendants' evidence. Plaintiffs have provided this information despite being clear that they do not plan to rely on it to prove their case.

I. Plaintiffs have fully answered Interrogatory No. 6.

Manufacturer Interrogatory No. 6 asks Plaintiffs to identify 500 prescriptions of opioids written in each Plaintiff's jurisdiction in reliance on any alleged misrepresentations, omissions or other alleged wrongdoing by defendants. On December 31, 2018, in compliance with Discovery Ruling 13, Plaintiffs provided a lengthy and detailed response to Interrogatory No. 6. (*See* Ex. C to Manufacturers' Motion to Compel, Plaintiffs Supplemental Amended Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories, Submitted Pursuant to Discovery Ruling 13, dated December 31, 2018 "Plaintiffs' Supplemental Response").

Manufacturer Defendants now complain that Plaintiffs' responses were insufficient because they did not identify the specific misrepresentation, omission or wrongdoing that allegedly caused each specific prescription to be written; the specific sales representative(s), employee(s) or agent(s) or Defendants who made the misrepresentations and the recipient(s) of the alleged misrepresentations. (*See* Manufacturers' Motion to Compel at 2). This rehashes issues already decided by the Special Master.

Defendants raised the same arguments in connection with prior responses, and the Special Master ruled that "Plaintiffs have sufficiently identified the connections between the prescriptions and the misstatements at issue." (Discovery Ruling 13 at 7). That ruling applies with equal force here. It makes no difference, as Defendants allege, that this statement came in the context of Interrogatory No. 7. The point is the same: the information produced identifies specific prescriptions that were written in reliance on alleged misrepresentations, omissions and other alleged wrongdoing, and Plaintiffs' Supplemental Response lists multiple false statements that were made by Defendants and the ways in which Defendants disseminated those statements – publicly; via sales representatives, CMEs and speakers; in articles and treatment guidelines; and in other ways described in Plaintiffs' Supplemental Responses. (*See*, Ex. C to Manufacturers' Motion to Compel at 5-15).

As Plaintiffs have repeatedly asserted, Plaintiffs do not intend, and have never intended, to demonstrate specific reliance by these medical professionals on a prescription-by prescription basis. (*See, id.* at 2.) This is not how prescribers operate: they do not link specific marketing statements (if they could even recall them) to a decision to begin or maintain a specific patient on opioids, or to increase their doses. Even if they did, it is unlikely that the prescribers would recall which misrepresentations were made by which specific Defendant representatives and Plaintiffs would still not have this information in their possession, custody or control. Instead, Plaintiffs allege that, collectively, Defendants' misrepresentations changed the standard of care for prescribing opioids, giving prescribers and patients a false sense of confidence that opioids could be used long-term, often

Special Master Cohen

January 8, 2019

Re: Response to Manufacturer Defendants' Renewed Motion to Compel

Page 4

at high doses, and that patients' pain would decrease, their function and quality of life would improve, and patients would not become addicted or suffer other adverse consequences. Plaintiffs do not assert that they will prove their case by proving prescribers relied on a specific misrepresentation made by a specific representative of Defendants in writing specific prescriptions.

Moreover, Plaintiffs' response is in compliance with Discovery Ruling 5, in which the Special Master ruled:

For a given plaintiff: (1) the '500 prescriptions' referred to in Manufacturer Interrogatory Nos. 6 and 10 and Pharmacy Interrogatory Nos. 2 and 3 *may* all be the same 500 prescriptions; (2) the '200 specific prescriptions' referred to in Manufacturer Interrogatory Nos. 6 and 10 and Pharmacy Interrogatory Nos. 2 and 3 *must* all be the same 200 prescriptions; (3) the 300 persons identified in Manufacturer Interrogatory No. 7 *may* overlap with the 500 prescriptions; and (4) the '100 specific persons' identified in Manufacturer Interrogatory No. 7 *may* overlap with the '200 specific prescriptions'.

Discovery Ruling 5 (emphasis in original). This ruling has not been changed by Discovery Ruling 13. Plaintiffs have identified the requisite specific 500 prescriptions and have sufficiently identified the connections between the prescriptions and the misstatements at issue. Defendants' Motion to Compel a further response to Manufacturer Interrogatory No. 6 should be overruled.

II. Plaintiffs have completely responded to Interrogatory Nos. 6, 7 and 10.

In addition to Plaintiffs' Supplemental Response which answered Interrogatory No. 6 on December 31, 2018, Plaintiffs responded to Interrogatory Nos. 7 and 10 on November 2, 2018 (*see, e.g.,* Ex. E to Manufacturers' Motion to Compel, Cleveland's Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories and the National Retail Pharmacy Defendants' First Set of Interrogatories) and produced two spreadsheets with their November 2 Responses ("Plaintiffs November 2 Responses"). Exhibit A is a spreadsheet that identifies 500 patients by name in the relevant jurisdictions who have not been treated for cancer, who have been diagnosed with Opioid Use Disorder and who were prescribed daily doses of opioids of 150 MME or higher. Exhibit B is a spreadsheet that identifies 300 individuals in Plaintiffs' jurisdictions who died from overdoses. Plaintiffs fully responded to the Interrogatories, including by affirmatively seeking out and obtaining data from third-parties, and have provided Defendants with information sufficient to answer the Interrogatories and to enable them to defend themselves.

Nonetheless, in an effort to compromise and to meet Defendants' concerns, Plaintiffs will produce this week a revised spreadsheet identifying approximately 730 additional patients who were prescribed daily doses of opioids of 120 MME or higher.

Special Master Cohen

January 8, 2019

Re: Response to Manufacturer Defendants' Renewed Motion to Compel

Page 5

A. Plaintiffs have Identified Individuals and Prescriptions Linked to Each Defendant and will continue to supplement this response.

At the outset, Plaintiffs note that Defendants are not arguing that Plaintiffs have not produced enough information put them on notice of the data Plaintiff may rely on or to mount their defense. Instead, Defendants complain that Plaintiffs have not produced *enough* information related to prescriptions or persons prescribed an opioid sold by a certain few of the Defendants. Plaintiffs have substantially complied with the requirements Discovery Ruling 5 in their responses to Interrogatory Nos. 6, 7 and 10. Discovery Ruling 5 orders that for Interrogatory Nos. 6 and 10: "Plaintiffs' responses must include at least 10 prescriptions for an opioid sold by each manufacturing defendant." (Discovery Ruling 5 at 2, 4). Similarly, for Interrogatory No. 7, Discovery Ruling 5 states that: "Plaintiffs' responses must include at least 10 persons for an opioid sold by each manufacturing defendant." (Discovery Ruling 5 at 3). Defendants' Motion to Compel ignores that Plaintiffs have, collectively, identified the requisite persons and prescriptions. Defendants also overlook the fact that any information provided for Akron is also information for Summit County, where Akron is located, and any data given for Cleveland is also information for Cuyahoga County, where Cleveland is located.

Defendants also protest that Plaintiffs group together certain Manufacturers. To the extent Plaintiffs have identified persons prescribed an opioid sold by a family or group of Defendants, this is because those companies are related and sold the relevant prescriptions. For example the Actavis-Allergan defendants say that Allergan, Actavis, Allergan Finance, LLC and the tax-avoidance offshore parent known as Allergan plc should be treated as "separate companies" for purposes of Interrogatory No. 7. (Manufacturers' Motion to Compel at 4). This is incorrect – they are a corporate family. Actavis and its predecessors, which made and sold the opioid drugs at issue, merged with Allergan in 2014, and in 2016 the merged companies sold their generic opioid lines to Teva. The Allergan/Actavis defendants have admitted this in the past, and the Court has accepted it. *See, e.g.* Discovery Ruling 4 at 1 (noting that "prior to 2016, Allergan marketed both branded opioid drugs (e.g., Kadian and Norco) and also generic opioid drugs (e.g., generic versions of Kadian and Oxycodone)"). Defendants have responded to discovery as a single family, have never previously made a distinction between the merged companies, and have shown no reason to make one now. All of the hazardous prescriptions Plaintiffs identified were filled using drugs made by this corporate family prior to their divestment of the generic opioids lines to Teva. Plaintiffs identified more than 10 persons in Exhibit A who were prescribed drugs by the Actavis-Allergan defendants.

Moreover, Plaintiffs made their good faith response despite the fact that Defendants have failed to answer the same discovery request (Interrogatory 17 to Manufacturer Defendants, No 21 to Purdue Pharma Defendants). As Plaintiffs have made clear, the responsive information is not based on Plaintiffs' own claims data but from information produced by other parties in discovery, public records and a Rule 45 subpoena. Because of Defendants' own failure to provide prescription-level data, Plaintiffs were forced to respond without the benefit of full discovery.

Special Master Cohen

January 8, 2019

Re: Response to Manufacturer Defendants' Renewed Motion to Compel

Page 6

The above aside, Plaintiffs will agree to identify additional prescriptions and will produce a revised spreadsheet identifying an additional 730 patients who were prescribed daily doses of opioids of 120 MME or higher. This will provide another 86 patients who were prescribed an opioid sold by the Actavis-Allergan defendants, another 69 patients who were prescribed an opioid sold by the Teva-Cephalon Defendants and raises the number of patients who were prescribed an opioid sold by Janssen to 10 as required by Discovery Ruling 5.

Defendants' final complaint is that Plaintiffs have purportedly failed, in some instances, to provide the basis for Plaintiffs' assertion that the prescription was unauthorized, medically unnecessary, ineffective or harmful because Plaintiffs contend that all prescriptions were unnecessary. Defendants cannot force Plaintiffs to change their responses simply because they do not like them. Plaintiffs have been clear, from the outset of this litigation, of their contention that by misrepresenting the risks and benefits of opioids, particularly for long-term use and at high doses, and for non-cancer chronic pain, Manufacturer Defendants deprived *all* prescribers and patients from having accurate information about the dangers and appropriateness of opioids, rendering all prescriptions improper. (*See, e.g.*, Plaintiffs' November 2 Responses, Response to Interrogatory No. 10, "Bellwether Plaintiffs further contend that, by misrepresenting the risks, benefits, and superiority of opioids, particularly for use long-term and at high doses, including, but not limited to, through sales visits, continuing medical education and speaker programs, publications and websites, and treatment guidelines, Manufacturer Defendants deprived prescribers and patients of the ability to make informed choices about whether, when, and which opioids to prescribe and use, for how long, and at what doses.") Moreover, all of the prescriptions identified by Plaintiffs resulted in diagnoses of Opioid Use Disorder (or fatalities of those individuals identified in Exhibit B); by definition, each prescription caused the harm of opioid addiction or death.

The responses to Interrogatory Nos. 6, 7 and 10 provide Defendants with a sufficient understanding of the facts and theories at issue in this case.

B. The Claims Data that Defendants Seek is not in Plaintiffs' Possession, Custody or Control.

Defendants further complain that Plaintiffs have not identified the conditions for which each prescription was written and refused to provide the condition for which each prescription was written. As Plaintiffs explained repeatedly to Defendants, Plaintiffs responded with the information they had at the time. None of the individuals identified in the original Exhibit A were insured by Plaintiffs. Plaintiffs do not have the underlying claims data for these individuals in their possession, custody or control, and were never in possession of this information. Moreover, Plaintiffs have provided Defendants with the criteria used to determine that each individual had an opioid use disorder.

The third party from whom Plaintiffs obtained the information originally refused to provide medical diagnosis information due to concerns regarding running afoul of Part 2 restrictions on

Special Master Cohen

January 8, 2019

Re: Response to Manufacturer Defendants' Renewed Motion to Compel

Page 7

disclosure. The same restrictions remain in effect and the concerns are even more applicable to this data set.

To facilitate the production of claims data for individuals insured by the CT1 Plaintiffs, the parties worked together to negotiate and implement a protocol intended to identify patient records subject to Part 2 restrictions and to produce the Part 2 data in de-identified form. As a result of that effort, Plaintiffs produced more than 22 million medical and pharmacy claims associated with 84,645 patients on December 18, 2018.

But the protocol implemented with respect to production of claims data for individuals insured by the CT1 Plaintiffs does not permit production of medical claims associated with the prescriptions identified in response to these interrogatories. The claims data already produced included individuals insured by the CT1 Plaintiffs who received *any* opioid prescription. In contrast, the criteria applied to respond to the interrogatory is limited to the opioid prescriptions most prone to abuse (more than 120 MME/day). That criteria, understandably, yields a much higher proportion of medical claims that are subject to Part 2 restrictions because individuals receiving abuse-prone prescriptions also are more likely to have sought or received substance abuse disorder treatment, including from "Part 2 Providers" (providers whose records are subject to Part 2 disclosure restrictions).

Identifying only the abuse-prone prescriptions in response to these interrogatories does not implicate Part 2 concerns because such pharmacy claims do not indicate whether a "Part 2 Provider" made the substance abuse disorder diagnosis. Therefore, the information Plaintiffs have produced (or are producing) does not identify which patients are subject to Part 2 restrictions. But adding the medical claims to this equation (including identifying the providers) permits this analysis, and thus triggers the federal restrictions.

Federal law therefore precludes disclosure of medical records in response to these interrogatories, unless the Court seeks to order production of such material consistent with 42 C.F.R. § 2.64, which requires notice to each affected individual.

For the reasons laid out above, Plaintiffs have more than sufficiently responded to Defendants' Interrogatories and their Motion to Compel should be denied.

Respectfully submitted,

/s/ Linda Singer

cc: Defense Counsel Listserve